



OAR Inter-IC HIV/AIDS Coordinators Meeting

Guiding Principles & Draft Concepts for DAIDS 2006 Clinical Research Networks

March 22, 2004





Goals for today's meeting

- What are our goals for 2006-2011?
- What we are proposing
- How does our draft plan address/impact your IC's HIV/AIDS priorities?
- Can you suggest better/improved ways to design/structure the networks to meet the scientific priorities?



Timetable for FY06 Clinical Research Network Solicitations

- | | |
|------------------|----------------------------|
| • January 2004 | ARAC review draft concepts |
| • May 2004 | ARAC review final concepts |
| • Fall 2004 | Release of solicitations |
| • Fall 2004 | Pre-application meetings |
| • Summer 2005 | Receipt of applications |
| • Fall 2005 | Review of applications |
| • Jan-March 2006 | Awards |



What we've learned so far

Strengths of networks

- Bring together expert investigators in collaborative groups
- Peer-review hones ideas & improves research quality
- Provide continuity for strategic planning and product development
- “Re-usable” infrastructure promotes efficiency, data quality & comparability



What we've learned so far

Shortcomings of networks

- Protocol development can be slow
- Time commitment can be huge
- Can be overly risk averse or dogmatic
- Leadership can be seen or function as closed shops
- Can function in isolation from one another



Guiding Principles for Evolving the Networks

- Address domestic and international clinical research questions of highest priority
- Coordinate HIV/AIDS prevention and treatment research for the best clinical science
- Maximize scientific opportunities through coordinated research
- Increase efficiency through resource sharing
- Build and sustain clinical research capacity in resource poor settings
- Partner with organizations with complementary strengths



Putting principles into action

- Coordinated leadership & increased accountability
- Coordinated development of international sites that can conduct linked prevention and treatment research
- Sharing of laboratory resources and protocols
- Common data elements and data entry interfaces
- Coordinated specimen management guidelines
- Shared/standardized training for common needs
- Inter-network meetings
- Coordinated approach to clinical research product acquisition, distribution and provision
- Greater efficiency with all resources, human and \$\$



Draft Concepts for DAIDS Clinical Research Networks

Prototype Network Solicitation Framework

Leadership Group

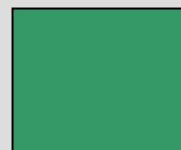
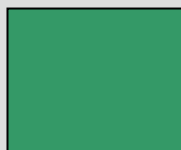
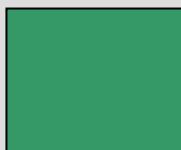
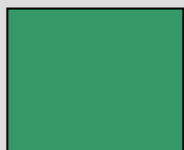
Operations

Biostatistics

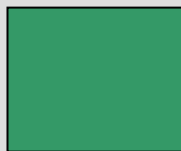
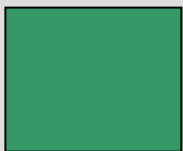
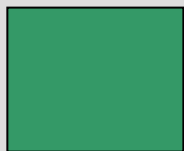
Data
Management

Specialized
Labs

International Sites



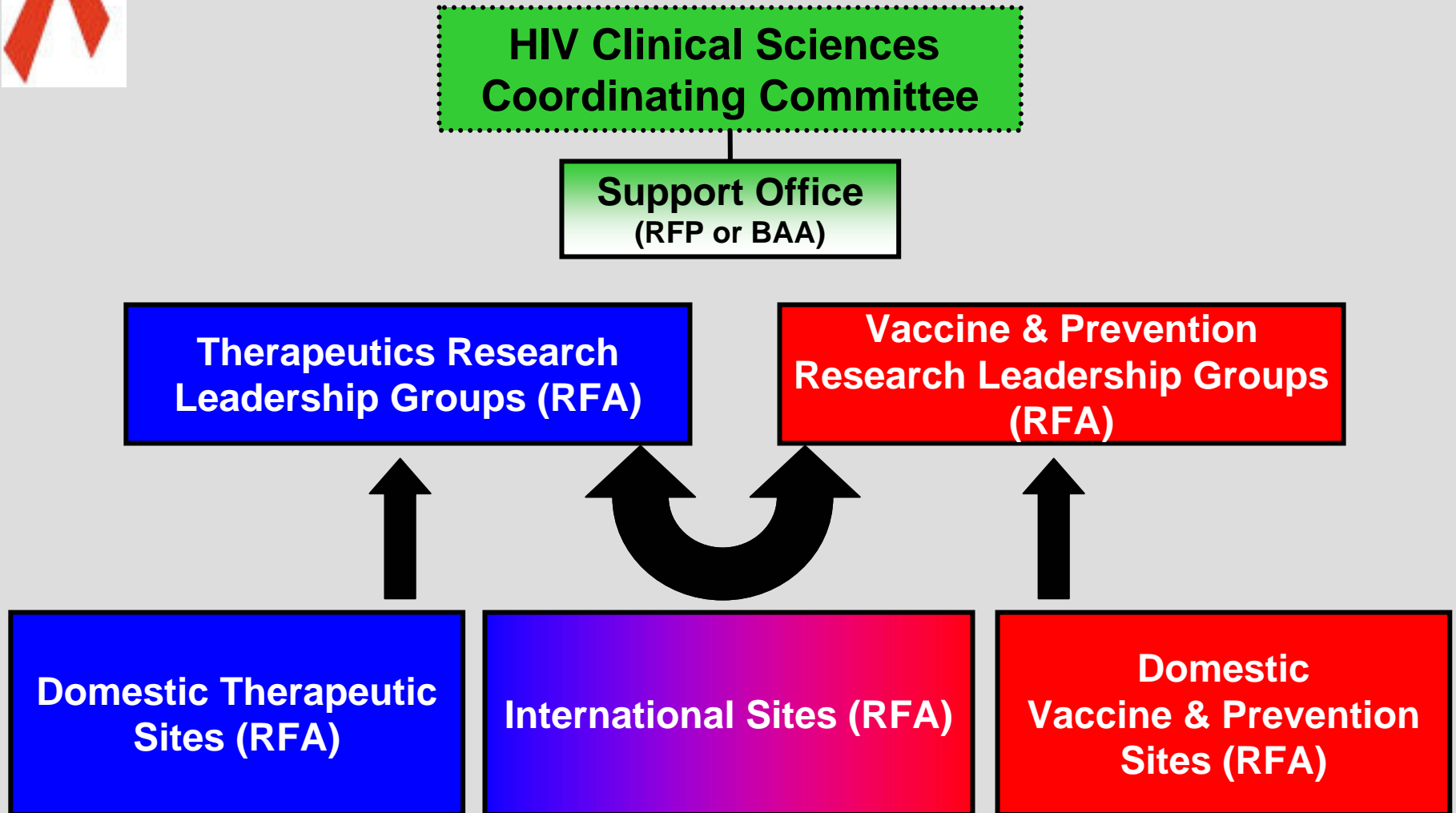
Domestic Sites



**HIV Clinical Research Management
Support Contract**



Draft Concept Plan #1





Draft Concept Plan #2

External Scientific Review Groups

Managing Partners Committee

Leadership Groups (RFA)

Domestic Sites (RFA)

International Sites (RFA)

DAIDS Global Clinical Research Matrix

Managing Partners Committee

**Support
Office**

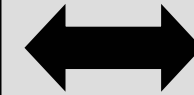
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A**

**Network
B**

**Network
C**

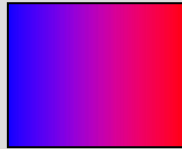
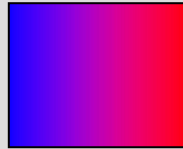
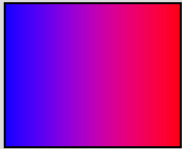
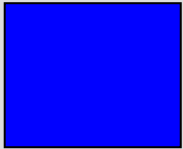
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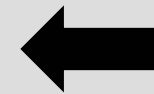


**HIV Clinical Research
Management Support
Contract**

International Sites



Domestic Sites



Consultations (pre-ARAC)

- October 2001: 1st Network Leaders Meeting, Focus: Integrating Prevention & Treatment Research; Initiate HPTN 052/AACTG 5175 collaboration
- November 2002: AACTG & HPTN Chairs, Focus: HPTN 052/AACTG 5175 coordination
- June 2, 2003: 2nd Network Leaders Meeting*, Focus: Structuring the clinical research effort
- August 14, 2003: Monthly Network Leadership CC; Focus: Establishing Monthly CC for RFA FY '06
- September 2003: ARAC Meeting, Focus: ARAC recommendation re FY '06 Network Recompensation
- September 17, 2003: 3rd Network Leaders Meeting, Focus: Addressing Scientific Priorities Discussion: "Developing a Model for Clinical Research Networks in a Global Environment"
- October 15, 2003: Monthly Network Leadership CC; Focus: Scientific Integration
- November 19, 2003: Monthly Network Leadership CC; Focus: Preparation for December 9th Meeting
- December 9, 2003: 4th Network Leaders Meeting, Focus: Network Leadership plan
- December 9, 2003: HIV/AIDS Community-based organizations/constituencies, Focus: Discussion and Input
- December 10, 2003: AACTG* Executive Committee and Principal Investigators, Focus: Discussion and input
- December 17, 2003: Monthly Network Leadership CC; Focus: Follow-up to Network Leadership Plan
- January 21, 2004: Monthly Network Leadership CC; Focus: Network Leadership Plan/Timeline

Consultations (post-ARAC)

- January 22, 2004: OAR Meeting: Pre-Briefing regarding ARAC presentation of DAIDS draft concept
- January 26, 2004: ARAC Meeting, Focus: DAIDS Presentation – Future of Clinical Research ‘draft concept’
- February 8, 2004: HVTN*, HPTN**, ESPRIT* & AIDREP* Executive Committees and Principal Investigators; Focus: Review of DAIDS Jan ARAC ‘draft concept’, discussion and input (HPTN Summary attached)
- February 19, 2004: Meeting with Dr. Cathy Wilfert/EGPAF re Peds during HPTN meeting, Focus: Review of DAIDS Jan ARAC ‘draft concept, discussion and input (more Peds input needed)
- February 18, 2004: Monthly Network Leadership Plan; Focus: Network Leadership Plan Update
- February 23, 2004: Conference Call with AIEDRP Principal Investigators; Focus: Review of DAIDS ‘draft concept’
- February 25, 2004: DAIDS All Staff Meeting: DAIDS Draft Concept RFA FY ‘06
- March 3, 2004: Pre- Meeting with FAPP HIV Research Working Group*: Focus: Requested meeting with Dr. Fauci, Review DAIDS Draft Concept prior to meeting with Dr. Fauci on March 9th
- March 9, 2004: Meeting with FAPP HRWG*: Focus: Discussion with Dr. Fauci re DAIDS draft concept
- March 9, 2004: Meeting with Larry Corey/HVTN: Re Network Leadership Plan and DAIDS Draft concept
- March 10, 2004: NCI Meeting: Focus: Inter IC Collaboration/Scientific Priorities
- March 11, 2004: NICHD Meeting: Focus: Inter IC Collaboration/Scientific Priorities
- March 11, 2004: Meeting with Cross Network CABS*: Scheduling a CC for DAIDS draft concept
- March 12, 2004: NIMH Meeting; Focus: Inter IC Collaboration/Scientific Priorities
- March 16, 2004: Global HVTN CAB* Community Educator Meeting: Focus: DAIDS draft concept
- March 17, 2004: Monthly Network Leadership Plan; Focus HIV Clinical Research Management Support Contract
- March 18, 2004: CC with Toby Clark*, Global HTVN CAB re: DAIDS draft concept
- March 22, 2004: Office of AIDS Research led meetings with NIH IC HIV/AIDS Coordinators & program leadership, Focus: Review of DAIDS Jan ARAC ‘draft concept, discussion and input
- March 25, 2004: AACTG Retreat Community Constituency* Meeting; Focus: DAIDS Draft Concept
- March 25, 2004: AACTG Retreat PI Meeting; Focus: DAIDS Draft Concept